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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53788

January 29, 1998

Mr. Jon C. Gorder, President
New Milk Inc.
142 S. Aurora
Stockton, CA 95202

WARNING LETTER

Dear Mr. Gorder:

An inspection of your medicated feed mill by FDA Investigator Alice A. Blair on December 4 through 12, 1997, revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not confirm to, or are not operated in conformity with Title 21, Code of Federal Regulations, Part 225. Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Our inspection found that you have failed to follow procedures for maintaining the reconciliation and inventory of Category I drugs and medicated type B feeds containing neomycin and oxytetracycline; no original batch records are maintained or reviewed regarding mixing and distribution of medicated type B products; you are not following your procedures you established for the inspection, flushing, maintenance and calibration of equipment used in

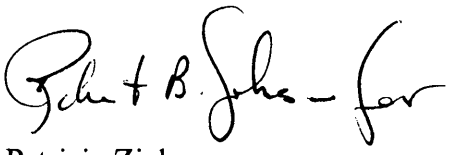
the production of medicated and non-medicated feeds; you are not following procedures for properly labeling your flushing materials used after the production of medicated feeds.

You should take prompt action to correct these violations, and you should establish procedure whereby such violations do not recur. Should you fail to promptly correct these violations, the Food and Drug Administration is prepared to invoke regulatory and/or administrative sanctions provided under the law. These include but are not limited to seizure and/or injunction.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are met. Until the violations have been corrected and verified by the FDA, the Center for Veterinary Medicine will not approve a medicated feed application for your facility.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Alice A. Blair, Investigator, P.O. Box 1179, Stockton, California 95201.

Sincerely yours,



Patricia Ziobro
District Director
San Francisco District